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## **FACSIMILE TRANSMISSION**

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May 25, 2000

VIA FACSIMILE 703-308-8724

Examiner Bradley L. Sisson

Assistant Commissioner for Patents

Washington D.C. 20231

Re:

U.S. Patent Application Serial No. 09/475,958

For: CELL CONCENTRATION AND LYSATE CLEARANCE USING

PARAMAGNETIC PARTICLES

File No. 16026-9038

## Dear Examiner Sisson:

Thank you for agreeing to speak with Grady Frenchick, Rex Bitner, and me over the telephone earlier today. As a follow-up to our conversation, below is a summary of the changes to the claims which we agreed to have you make to the above-cited application, in order to further prosecution thereof. The only change made in the proposed edits, below, since our conversation earlier today, was to move the Markush group describing the "magnetic particles" from immediately after introduction of the term "magnetic particles" to the end of the phrase. That additional change is proposed herein to further clarify the subject matter which Applicants consider to be the invention.

- 1. A method of using magnetic particles to concentrate or harvest cells, comprising the steps of:
  - (a) combining [a solution with] cells [contained therein] with magnetic particles under conditions wherein the cells form a complex with the magnetic particles, wherein said magnetic particles are selected from the group consisting of: pH-dependent ion exchange magnetic particles, and silica magnetic particles consisting essentially of a magnetic core coated with siliceous oxide having a hydrous siliceous oxide adsorptive surface; and
  - (b) isolating the complex from the solution by application of magnetic force.
- 8. A method of clearing a solution of disrupted biological material, according to steps comprising:
  - (a) providing a solution comprising a disrupted biological material and a target nucleic acid;



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- (b) combining the solution with second magnetic particles under conditions wherein the disrupted biological material selectively forms a complex with the second magnetic particles, wherein said second magnetic particles are selected from the group consisting of: pH-dependent ion exchange magnetic particles, and silica magnetic particles consisting essentially of a magnetic core coated with siliceous oxide having a hydrous siliceous oxide adsorptive surface; and
- (c) separating the complex from the solution by application of magnetic force.
- 21. A method of isolating a target nucleic acid from a disrupted biological material, comprising the target nucleic acid, a first non-target material, and a second non-target material, comprising the steps of:
  - (a) combining a solution of the disrupted biological material with first magnetic particles under conditions wherein the first non-target material selectively forms a first complex with the first magnetic particles, wherein said first magnetic particles are selected from the group consisting of: pH-dependent ion exchange magnetic particles, and silica magnetic particles consisting essentially of a magnetic core coated with siliceous oxide having a hydrous siliceous oxide adsorptive surface;
  - (b) separating the first complex from the solution of disrupted biological material by application of magnetic force, forming a cleared solution comprising the target nucleic acid and the second non-target material;
  - (c) combining the cleared solution with second magnetic particles under conditions wherein the target nucleic acid adsorbs to the second magnetic particles, forming a second complex;
  - (d) isolating the second complex from the cleared solution;
  - (e) washing the second complex by combining the second complex with a wash solution and separating the second complex from the wash solution by magnetic force; and
  - (f) combining the washed second complex with an elution solution, under conditions wherein the target material is desorbed from the second magnetic particles.

We also agreed to have the numbering of claims 30-36, as filed, changed to claims 28-34 to correct a typographic error in the claims as filed. Finally, we agreed to cancel [renumbered] claims 30-34, without prejudice, if the cancellation of those claims would further prosecution of the above-cited application.



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You indicated that if the above-cited amendments to the claims were found by the Examiner to be acceptable, we might need to have new Declarations executed by the inventors. We expressed a willingness to have new Declarations signed, once the patentability of the claims, after amendment as shown above is agreed upon.

Please feel free to contact Grady Frenchick or me if at any time you have questions on any of the above, or if you require any further information from us before preparing what we hope will be a first Office Action with a Notice of Allowance.

Sincerely yours,

MICHAEL BEST & FRIEDRICH LLP

Karen B. King

KBK:djf